



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/553,630

08/21/2006

Carin Widerstrom

15041.0010USWO

6047

23552 7590 08/03/2010
MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

JACOBSON, MICHELE LYNN

ART UNIT

PAPER NUMBER

1782

MAIL DATE

DELIVERY MODE

08/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/553,630 | Applicant(s) WIDERSTROM, CARIN | |
| | Examiner MICHELE JACOBSON | Art Unit 1782 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/10 has been entered.

Election/Restrictions

2. Claims 15 and 16 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/24/10. Applicant has requested on page 6 of the remarks that restricted claims 15 and 16 be included for examination. However, applicant has failed to provide any arguments to address the reasons for restriction stated in the previous office action.
3. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

4. Claim 1 is objected to because of the following informalities: Claim 1 has been amended to recite the limitation “a paper layer on outside of the sachet”. In order to be grammatically correct, this limitation should recite “a paper layer on *the* outside of the sachet” Appropriate correction is required.

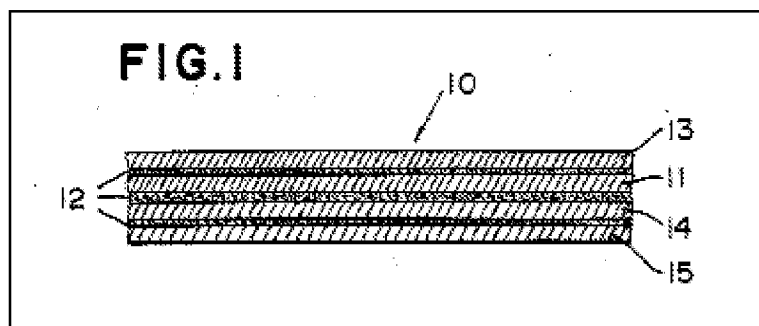
Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-14 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. U.S. Patent No. 4,360,550 (hereafter referred to as Asakura).

7. Asakura teaches a packaging pouch for packing relatively heavy materials such as medicines comprising a laminate film. (Col. 1, lines 8-13, Fig. 1) The laminate film comprises a base film (11) of



Art Unit: 1782

paper or aluminum foil. When paper is used the thickness is recited to be in the range between 40-90 g/m². (Col. 3, lines 63-66) When Al foil is used, the thickness is recited to be in the range of between 7 to 30 µm. (Col. 4, lines 5-8)

8. The base layer (**11**) is recited to be adhered between two HDPE layers, (**13**) and (**14**), having a thickness between 10-50 µm. (Col. 4, lines 9-23) A sealant layer (**15**) comprising low density polyethylene in a thickness between 15 to 120 µm is laminated on one of the HDPE layers. (Col. 5, lines 25-53) In the examples of Asakura, the sealant layer is disclosed to have a thickness of 30 µm. (Col. 6, line 45) Adhesive layers, (**12**), are disposed between all of the layers of the laminate.

9. Asakura is silent regarding using an Al foil layer and paper layer simultaneously with the paper layer being disposed on the outside of the pouch, the bonding layer having a weight per unit area and thickness less than the sealing layer, the identity of the bonding layer, the weight per unit area of the bonding layer, a weight per unit area of the sealing layer between 30-40 g/m² or 35 g/m² and a thickness of the barrier layer of 12 µm.

10. Regarding claim 1: Asakura discloses a laminate comprising the following layers in order from outside to inside with bonding layers in between: polyethylene layer/aluminum layer/HDPE layer/LDPE sealant layer. Asakura also discloses the utility of paper layers for laminates such as that disclosed and that the laminate disclosed is intended to be used for packaging "relatively heavy materials". It would have been obvious to one having ordinary skill in the art at the time the invention was made to have disposed a paper layer on top of the layer (**13**) disclosed by Asakura in order to

Art Unit: 1782

provide additional strength to the laminate disclosed. Additionally, an exterior paper layer would have provided an outside surface to the pouch disclosed by Asakura that would have been well suited for printing of labels. A laminate of this structure would have comprised the following layers from outside to inside with bonding layers in between: paper layer/polyethylene layer/aluminum layer/HDPE layer/LDPE sealant layer. The examiner interprets the polyethylene layer of this embodiment to read on the limitation of "barrier layer" claimed in claim 1. This obvious modification of the laminate of Asakura would have produced a pouch with the same structure as claimed in claim 1.

11. While Asakura is silent regarding the thickness of the bonding layer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable of thickness of the bonding layer recited by Asakura in order to provide the best adhesion and strength to the laminate while minimizing the amount of material necessary to achieve an acceptable amount of strength and adhesion. This obvious optimization of a result effective variable would have produced a bonding layer with a weight per unit area (a value directly dependent on thickness) relative to the thickness of the sealing layer as recited in claim 1 and a weight per unit area and thickness as recited in claims 6-8.

12. Regarding claim 2: Although the modification of Asakura suggested above includes bonding layers between each of the layers of the paper layer/polyethylene layer/aluminum layer/HDPE layer/LDPE sealant layer laminate, the examiner takes official notice that it is well known in the polymer arts that polyethylene layers possess heat fusible adhesive properties or may be rendered adhesively activated by the

Art Unit: 1782

application of corona discharge and could be relied upon to provide adhesion between the paper and aluminum layer and the aluminum and LDPE sealant layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have relied upon heat fusion of the oriented polyethylene layer or adhesive activation by means of corona discharge of the oriented polyethylene layers of Asakura between the paper and aluminum layers in the modified invention of Asakura to provide bonding between these two layers to provide a laminate with a simpler construction. This obvious use of techniques well known in the art would have produced the invention as claimed in claim 2.

13. Regarding claims 3-5: Asakura recites that the paper layer has a weight per unit area of 40-90 g/m². In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)

14. Regarding claims 9, 10 and 17-20: Asakura recites that the sealing layer be between 15-120 µm thick which encompasses the range claimed in claim 9. The sealing layer is recited to comprise an LDPE with a density less than 0.92 g/cm³. When converted for a layer 15 µm thick, the LDPE sealing layer would have a mass per unit area of 13.8 g/m², and a 120 µm thick sealing layer as recited in the examples would have a mass per unit area of 110.4 g/m². Therefore a range of mass per unit area of 13.8 g/m² to 110.4 g/m² can reasonably be ascertained by one of ordinary skill in the art. This range encompasses the ranges of mass per unit area of the sealing layer claimed

Art Unit: 1782

in claims 10 and 17-19. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)

15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable of thickness of the sealing layer recited by Asakura in order to provide the best adhesion and strength to the laminate while minimizing the amount of material necessary to achieve an acceptable amount of strength and adhesion. Such routine optimization would have produced a sealing layer with a weight per unit area (a value directly dependent on thickness) as recited in claim 20.

16. Regarding claims 11 and 21-25: The HDPE layer interpreted by the examiner to read on the barrier layer iii) of claim 1 is recited to be between 10-50 μm thick which encompasses the ranges claimed in claims 11 and 21-24. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the result effective variable of thickness of the barrier layer recited by Asakura in order to provide the most desirable barrier properties to the laminate while minimizing the amount of material necessary to achieve an acceptable barrier property.

Art Unit: 1782

Such routine optimization would have produced a barrier layer with a thickness as recited in claim 25.

17. Regarding claims 12-14: Asakura clearly recites that the pouch of the invention is useful for medicines which is interpreted by the examiner to read on the pharmaceutical formulations claimed in claim 12. While there is no disclosure that the pouch disclosed by Asakura is used for mesalazine or a pharmaceutically acceptable salt thereof as presently claimed, applicants attention is drawn to MPEP 2111.02 which states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the *purpose or intended use results in a structural difference between the claimed invention and the prior art*. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

18. It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. packaging mesalazine or a pharmaceutically acceptable salt thereof, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art pouch disclosed by Asakura and further

Art Unit: 1782

that the prior art structure which is a pouch identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Therefore, the modified invention of Asakura reads on the limitations of claims 13 and 14.

Response to Arguments

19. Applicant's arguments filed 2/24/10 have been fully considered but they are not persuasive.

20. Applicant has requested on page 6 of the remarks that restricted claims 15 and 16 be included for examination. However, applicant has failed to provide any arguments to address the reasons for restriction stated in the previous office action. Therefore, applicants request for examination of these claims is not granted.

21. Applicant asserts on page 7 of the remarks that "the Asakura et al. reference requires that a film layer, not a paper layer, be on the outside of its container for a reason that is not relevant to the presently claimed invention". It is unclear to the examiner what citation in Asakura applicant presumes supports this assertion. There is no explicit statement in Asakura that the exterior layer of the pouch disclosed is *required* to be polymeric material. The Asakura references relies upon two HDPE layers having different orientations in order to provide a pouch which may be torn along a linear cut line. (Col. 2, lines 6-17) There is no disclosure that in order for this mechanism to function, one of the oriented HDPE layers is "required" to be on the exterior of the

Art Unit: 1782

pouch. As enumerated in the rejection above, the obvious modification of Asakura would have resulted in the invention claimed.

22. Applicant discusses several perceived advantages of the claimed invention on pages 7 and 8 of the remarks, however, applicant fails to enumerate why any of these properties should be taken into account since these advantages are neither described as being unexpected or demonstrated not being provided by the modification of Asakura. Additionally, there are no claim limitations instantly pending relating to these perceived advantages. Therefore, the examiner does not find these assertions persuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Thursday 8:30 AM-7 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1782

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele L. Jacobson
Examiner /M. J./
Art Unit 1782

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782